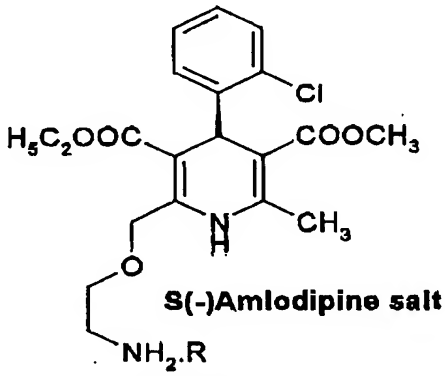
274/NF/03

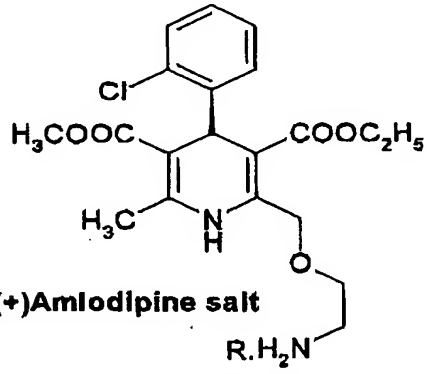
We claim:

1. A process for the preparation of pharmaceutically acceptable chiral salts of Amlodipine namely S(-) Amlodipine salts having formula (1) and R(+) Amlodipine salts having formula (2)



S(-)Amlodipine salt

FORMULA-1



R(+)Amlodipine salt

FORMULA-2

wherein R is selected from the group consisting of benzenesulphoinic acid, succinic acid, maleic acid, oxalic acid and p-toluenesulphonicacid, wherein the salts of formula 1 and 2 are prepared without isolation of a free base with optical purity ranging between 96-99% the process comprising:

(a) reacting a solution of RS amlodipine base in an organic solvent with a solution of L(+) or D(-) tartaric acid in an organic solvent at temperature ranging from 20-35°C for a period ranging between 16-24 hrs., to obtain a solvate comprising an amlodipine tartarate salt;

(b) separating and reacting the amlodipine tartarate salt obtained in step (a) with an aqueous solution of an acid optionally in presence of an organic solvent, and at a temperature ranging between 20-40°C;

(c) adding water to the reaction mixture of step (b) to obtain the salt of formula 1 and 2, separating the salt of formula 1 and 2 and drying to obtain salt corresponding to the acid used in step (2) with ee ranging from 96-99%.

2. A process as claimed in claim 1 wherein the solvent used in step (a) is DMSO.

3. A process as claimed in claim 1 wherein the concentration of RS amlodipine base to solvent (DMSO) ranges between 0.16 to 0.40 gm/ml.

4. A process as claimed in claim 1 wherein the L(+)-tartaric acid or D(-) tartaric acid employed is 0.25 mole equivalent of the amlodipine base.

5. A process as claimed in claim 1 wherein the solvate obtained in step (a) is a precipitate comprising S(-) Amlodipine hemi D(-) tartarate mono DMSO solvate or R(+) amlodipine hemi L(+) tartarate mono DMSO solvate.
6. A process as claimed in claim 1 wherein the solvent used for salt formation in step (b) is selected from dimethylsulfoxide, isopropylacohol and ethanol.
7. A process as claimed in claim 1 wherein the cumulative ratio of water to solvent in steps (b) and (c) ranges between 5:1 to 8:1.
8. A process as claimed in claim 1 wherein the acid used in step (b) is selected from the group consisting of benzenesulfonic, maleic, oxalic acid and p-toluene sulfonic acid.
9. A process as claimed in claim 1 wherein the ratio of amlodipine tartarate salt to organic solvent in step (b) is in the range 1:1 to 1:5.
10. A process as claimed in claim 8 wherein the mole equivalent of benzene sulfonic acid used ranges between 0.9 to 1.
11. A process as claimed in claim 1 wherein the optical purity of R(+) amlodipine besylate or S(-) amlodipine besylate is improved from 95% to 99% .